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تعميم إداري رقم (3440) لسنة 2017

السادة / مدراء المناطق الطبية المحترمين
السادة / مدراء المستشفيات الحكومية والخاصة المحترمين
السادة / مدراء الصيدليات الحكومية والخاصة المحترمين
السادة / الأطباء والصيادلة ومساعدي الصيادلة المحترمين

الموضوع: تحذير من الاستخدام غير الضروري للمنتجات الحاوية على مادة Gadolinium في التصوير الشعاعي بالرنين المغناطيسي

نلفت انتباه جميع المخاطبين بهذا التعميم بأن وزارة الصحة ووقاية المجتمع تحذر من الاستخدام غير الضروري للمنتجات الحاوية على مادة Gadolinium و المستخدمة في تحسين التصوير بالرنين المغناطيسي مما يساعد الأطباء في تشخيص وعلاج عدد من الحالات الطبية. وقد استخدمت هذه المادة في تشخيص و علاج أكثر من 100 مليون مريض في جميع أنحاء العالم على مدى السنة 25 الماضية.

و بناءا على التحذيرات الصادرة من هيئة الغذاء والدواء الأمريكية و الوكالة الأوروبية للأدوية و جمعية مهنيي الأشعة في أمريكا الشمالية (RSNA) توصي وزرارة الصحة ووقاية المجتمع بالتالي:

- لا تستخدم مادة غادولينيوم في المرضى الذين يعانون من الفشل الكلوي الحاد أو المزمن.
- قد أظهرت العديد من الدراسات الأولية وجود تركيزات من مادة جادولينيوم المتبقية في أدمغة المرضى الذين لا يعانون من أمراض الكلى . ويجب الحذر لحين اكتمال الملاحظات السريرية الغير معروفة الآن.
- ينبغي عدم حرمان المرضى الذين بحاجة الى هذا المنتج المنقذ للحياة في تحسين وتعزيز التصوير بالرنين المغناطيسي .وفي الوقت نفسه، ينبغي أن تؤخذ في الاعتبار المخاطر المحتملة المرتبطة بتركيزات جادولينيوم المتبقية في الدماغ. وعليه يجب اتخاذ الاحتياطات الضرورية والتأكد من أن فوائده تفوق اضراره قبل الاستخدام لكل مريض على حده.

علما بان المنتجات الحاوية على المادة المذكورة اعلاه مسجلة لدى وزارة الصحة ووقاية المجتمع.

وفي حال حدوث أي أعراض جانبية يرجى ملئ الاستمارة الخاصة بالآثار الجانبية للدواء ADR والمتوفرة على البريد الالكتروني: http://www.cpd-pharma.ae. أو الاتصال على العناوين التالية:

هاتف: 2301448 -04 أو فاكس2301947 -04 أو البريد الالكتروني: pv @moh.gov.ae

و تفضلوا بقبول فائق الاحترام و التقدير

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صدر بديوان عام الوزارة/ادبي بتاريخ 16:- 4-2017

نسخة لـ :

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سعادة / مدير ادارة الدواء

مدير ادارة الدواء

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RSNA Statement on Gadolinium-Based MR Contrast Agents
Reviewed 3/17/2017

The Radiological Society of North America (RSNA) is committed to excellence in patient care through education and research.

- Radiologists, radiology technologists, radiology nurses and other radiology professionals are committed to conscientious implementation of imaging studies that utilize gadolinium-based contrast agents. Radiologists also apply appropriateness criteria in a variety of ways, including consultation with patients' physicians and other providers who order imaging examinations to guide the patient to the best procedure to address the clinical circumstance.

- Gadolinium-based contrast agents have been used for diagnosis and treatment guidance in more than 100 million patients worldwide over the past 25 years. These agents enhance the quality of MR images by altering the magnetic properties of nearby water molecules in the body. By improving the visibility of specific organs, blood vessels or tissues, contrast agents help physicians diagnose and treat a wide variety of medical conditions.

- Gadolinium-based contrast agents are approved by the FDA for use with MRI to provide improved images of body organs and tissues. Gadolinium-based contrast agents are also used for magnetic resonance angiography (MRA), an imaging procedure used to evaluate blood vessels.

- Gadolinium is a paramagnetic metal ion. Gadolinium-based contrast agents are manufactured by a chelating process, a procedure in which large organic molecules form a stable complex around the gadolinium. The chelate reduces the chances of toxicity that could result from exposure to gadolinium. This stable complex is eliminated predominantly via the kidneys.

- Gadolinium-based contrast agents are contraindicated in patients with severe acute or chronic renal failure, with a glomerular filtration rate (GFR) < 30, because of the risk of nephrogenic systemic fibrosis (NSF). NSF is a rare but serious systemic disease characterized by fibrosis of the skin and other tissues throughout the body.

- Several preliminary studies have demonstrated the presence of residual gadolinium concentrations in the brains of patients with no history of kidney disease. The clinical significance of this observation is unknown at this time, but warrants attention.

- Patients should not be unnecessarily deprived of crucial, sometimes life-saving medical data from gadolinium contrast-enhanced MRI. At the same time, the potential risk associated with residual gadolinium concentrations in the brain should be taken into consideration. This risk must be weighed against the clinical benefit of the diagnostic information or treatment result that MRI or MRA may provide for each individual patient.

Through its peer-reviewed journals and education programs, RSNA continually informs radiologists, medical physicists, radiation oncologists and other radiology professionals of the latest technologies and research developments designed to optimize dose and improve patient safety.

The RSNA Scientific Assembly and Annual Meeting, one of the world's largest annual medical meetings, provides a forum for the exhibition of state-of-the-art medical imaging equipment, the presentation of radiologic research findings and the exchange of knowledge in education courses and plenary sessions.

For more than 25 years, RSNA's Research and Education Foundation has sought to improve patient care by providing funding grants and awarding individuals and institutions that advance radiologic research, education and practice.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 March 2017
EMA/157486/2017
Media and Public Relations

PRAC concludes assessment of gadolinium agents used in body scans and recommends regulatory actions, including suspension for some marketing authorisations

Review finds evidence of gadolinium deposits in the brain after MRI body scans but no signs of harm

EMA's Pharmacovigilance and Risk Assessment Committee (PRAC) has recommended the suspension of the marketing authorisations for four linear gadolinium contrast agents because of evidence that small amounts of the gadolinium they contain are deposited in the brain.

The agents concerned are intravenous injections of gadobenic acid, gadodiamide, gadopentetic acid and gadoversetamide, which are given to patients to enhance images from magnetic resonance imaging (MRI) body scans.

The PRAC's review of gadolinium agents found convincing evidence of accumulation of gadolinium in the brain from studies directly measuring gadolinium in brain tissues and areas of increased signal intensity seen on MRI scan images many months after the last injection of a gadolinium contrast agent.

The companies concerned by this review have the right to request the PRAC to re-examine its recommendations.

The PRAC's final recommendations will be sent to the Committee for Medicinal Products for Human Use (CHMP) for its opinion. Further details will be published at the time of the CHMP opinion.

Although no symptoms or diseases linked to gadolinium in the brain have been reported, the PRAC took a precautionary approach, noting that data on the long-term effects in the brain are limited. Deposition of gadolinium in other organs and tissues has been associated with rare side effects of skin plaques and nephrogenic systemic fibrosis,[1] a scarring condition in patients with kidney impairment. Furthermore, non-clinical laboratory studies have shown that gadolinium can be harmful to tissues.

The four agents recommended for suspension are referred to as linear agents. Linear agents have a structure more likely to release gadolinium, which can build up in body tissues. Other agents, known as macrocyclic agents, are more stable and have a much lower propensity to release gadolinium. The

[1] See EMA review of gadolinium contrast agents in 2010.

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PRAC recommends that macrocyclic agents[2] be used at the lowest dose that enhances images sufficiently to make diagnoses and only when unenhanced body scans are not suitable.

Some linear agents will remain available: gadoxetic acid, a linear agent used at a low dose for liver scans, can remain on the market as it meets an important diagnostic need in patients with few alternatives. In addition, a formulation of gadopentetic acid injected directly into joints is to remain available because its gadolinium concentration is very low – around 200 times lower than those of intravenous products. Both agents should be used at the lowest dose that enhances images sufficiently to make diagnoses and only if unenhanced scans are not suitable.

For those marketing authorisations recommended for suspension, the suspensions can be lifted if the respective companies provide evidence of new benefits in an identified patient group that outweigh its risks or show that their product (modified or not) does not release gadolinium significantly (dechelation) or lead to its retention in tissues.

More about the medicine

Gadolinium contrast agents are used as contrast enhancers to improve image quality with MRI scans.

MRI is an imaging method that relies on the magnetic fields produced by water molecules in the body. Once injected, gadolinium interacts with the water molecules. As a result of this interaction, the water molecules give a stronger signal, helping to obtain a brighter image.

This review covers agents containing the following active substances: gadobenic acid, gadobutrol, gadodiamide, gadopentetic acid, gadoteric acid, gadoteridol, gadoversetamide and gadoxetic acid.

Most gadolinium-containing contrast agents have been authorised nationally in the European Union (EU). OptiMARK (gadoversetamide) is the only gadolinium contrast agent that was authorised centrally in the EU.

More about the procedure

The review of gadolinium contrast agents was initiated on 17 March 2016 at the request of the European Commission, under Article 31 of Directive 2001/83/EC.

The review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which made a set of recommendations. The PRAC's final recommendations will be sent to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.

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[2] Gadobutrol, gadoteric acid and gadoteridol

FDA Drug Safety Communication: FDA evaluating the risk of brain deposits with repeated use of gadolinium-based contrast agents for magnetic resonance imaging (MRI)

[7-27-2015]

Safety Announcement

The U.S. Food and Drug Administration (FDA) is investigating the risk of brain deposits following repeated use of gadolinium-based contrast agents (GBCAs) for magnetic resonance imaging (MRI). MRIs help detect abnormalities of body organs, blood vessels, and other tissues. Recent publications in the medical literature have reported that deposits of GBCAs (See Table 1) remain in the brains of some patients who undergo four or more contrast MRI scans, long after the last administration.[1-21] It is unknown whether these gadolinium deposits are harmful or can lead to adverse health effects.

FDA, including its National Center for Toxicological Research (NCTR), will study this possible safety risk further. We are working with the research community and industry to understand the mechanism of gadolinium retention and to determine if there are any potential adverse health effects. Based on the need for additional information, at this time, we are not requiring manufacturers to make changes to the labels of GBCA products.

To reduce the potential for gadolinium accumulation, health care professionals should consider limiting GBCA use to clinical circumstances in which the additional information provided by the contrast is necessary. Health care professionals are also urged to reassess the necessity of repetitive GBCA MRIs in established treatment protocols.

Patients, parents, and caregivers should talk to their health care professionals if they have any questions about the use of GBCAs with MRIs. This issue affects only GBCAs; it does not apply to other types of scanning agents used for other imaging procedures, such as those that are iodine-based or radioisotopes.

After being administered, GBCAs are mostly eliminated from the body through the kidneys. However, trace amounts of gadolinium may stay in the body long-term. Recent studies conducted in people and animals have confirmed that gadolinium can remain in the brain, even in individuals with normal kidney function.[1-21] Available information does not identify any adverse health effects.

We urge health care professionals, patients, and parents/caregivers to report possible side effects involving GBCAs to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Table 1. FDA Approved GBCAs

Brand name	Generic name
Ablavar	gadofosveset trisodium
Dotarem	gadoterate meglumine
Eovist	gadoxetate disodium
Gadavist	gadobutrol
Magnevist	gadopentetate dimeglumine
MultiHance	gadobenate dimeglumine
Omniscan	gadodiamide
OptiMARK	gadoversetamide injection
ProHance	gadoteridol

Data Summary

References

en Español (/Drugs/DrugSafety/ucm457153.htm)

Drug Safety Communication (/downloads/Drugs/DrugSafety/UCM455390.pdf) (PDF-43KB)

Related Information

- **Information on Gadolinium-Based Contrast Agents (/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm142882.htm)**
- **Questions and Answers on FDA's Adverse Event Reporting System (FAERS) (/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm)**

More in Drug Safety and Availability (/Drugs/DrugSafety/default.htm)

Drug Alerts and Statements (/Drugs/DrugSafety/ucm215175.htm)

Medication Guides (/Drugs/DrugSafety/ucm085729.htm)

Drug Safety Communications (/Drugs/DrugSafety/ucm199082.htm)

Drug Shortages (/Drugs/DrugSafety/DrugShortages/default.htm)

Postmarket Drug Safety Information for Patients and Providers (/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm)

Information by Drug Class (/Drugs/DrugSafety/InformationbyDrugClass/default.htm)

Medication Errors (/Drugs/DrugSafety/MedicationErrors/default.htm)

Drug Safety Podcasts (/Drugs/DrugSafety/DrugSafetyPodcasts/default.htm)

Safe Use Initiative (/Drugs/DrugSafety/SafeUseInitiative/default.htm)

Drug Recalls (/Drugs/DrugSafety/DrugRecalls/default.htm)

Drug Supply Chain Integrity (/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm)